



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

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WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Charles Fishelson, Vice President
Alfa Medical Equipment, Inc.
59 Madison Avenue
Hempstead, NY 11550

August 22, 2000

Ref: NYK-2000-92

Dear Mr. Fishelson:

During an inspection of your firm located at the above address, on July 17-26, 2000, our investigator determined that your firm manufactures dry-heat sterilizers. Dry-heat sterilizers are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act ("the Act").

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System/Good Manufacturing Practice (QS/GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Your firm's management with executive responsibility failed to establish its policy and objectives for, and commitment to, quality as required by 21 CFR 820.20(a).
2. Your firm failed to establish quality system procedures and instructions as required by 21 CFR 820.20(e).
3. Your firm failed to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met as required by 21 CFR 820.30(a).
4. Your firm failed to document the reason for the change in the design of the sterilizer heating unit on the engineering change order form per your SOP as required by 21 CFR 820.30(i).
5. Your firm failed to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system as required by 21 CFR 820.22.
6. Your firm failed to establish procedures for identifying training needs and to ensure that all personnel are trained to adequately perform their assigned responsibilities as required by 21 CFR 820.25(b).

Additionally, the above-stated inspection revealed that your devices are misbranded within the meaning of Section 502(t)(2) of the Act, in that your firm failed to develop, maintain and implement written Medical Device Reporting (MDR) procedures as required by 21 CFR 803.17.

This letter is not intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA 483 issued to you at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and/or quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

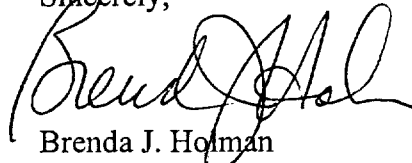
Federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the QS/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Bruce A. Goldwitz, Compliance Officer, Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433 (Tel. 718/340-7000 ext. 5582).

Sincerely,



Brenda J. Holman
District Director